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Patent Application

Inventors(s):	Susanne Arney Timofei Nikita Kroupenkine Donald Weiss	**Case:**	10-18-4
Serial No.:	10/798,064	**Filing Date:**	March 11, 2004
Examiner:	Brian E. Pellegrino	**Group Art Unit:**	3738
Title:	Drug Delivery Stent		

THE COMMISSIONER OF PATENTS AND TRADEMARKS
ALEXANDRIA, VA 22313-1450

SIR:

APPEAL BRIEF UNDER 37 CFR § 41.37

I. Real Party In Interest

The real party in interest is Alcatel-Lucent USA Inc., 600-700 Mountain Avenue, PO Box 636, Murray Hill, NJ, 07974-0636.

II. Related Appeals and Interferences

There are no related appeals or interferences.

III. Status of the Claims

At the time Applicants filed their notice of appeal, Claims 1-21 were in the case and being appealed. However, Claims 1-2 and 5-7 have been canceled pursuant to a recently filed amendment under 37 CFR § 41.33. If the Examiner enters that amendment, only Claims 3-4 and 8-21 would be on appeal.

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As suggested by SPE Janet Baxter (Technology Center 3700), two sets of claims are attached hereto: Appendix VIII(a) contains Claims 3-4 and 8-21 as they would appear in the case if the aforesaid amendment is entered, and Appendix VIII(b) contains Claims 1-21 as they appeared in the case at the time the notice of appeal was filed.

Claims 22-28 were canceled pursuant to a restriction requirement.

IV. Status of Amendments

An amendment under 37 CFR § 41.33 was filed on June 13, 2010, subsequent to the notice of appeal dated March 17, 2010.

V. Summary of Claimed Subject Matter

Applicants' invention on appeal relates to unique drug delivery stents configured to provide dynamic control of the hydrophobicity of a microstructured surface of the stent, whereby a drug (or other medicinal substance) is released from the interstices of the microstructure into body fluid. Examples of these stents are described in the specification from page 4, line 18 to page 12, line 7.

As set forth in independent claim 8, an implantable stent (e.g., element 60; FIG. 5) comprises a tubular member having an interior surface and an exterior surface, with a region of at least one of the surfaces being hydrophobic to a body fluid (e.g., layer 67; FIG. 3); the contact angle between a droplet of the body fluid (e.g., 40; FIG. 3) and the surface is greater than 90° (see, e.g., specification, page 7, lines 3-4). The hydrophobic surface region is provided with an array (e.g., element 62; FIGs. 3, 5) of microstructures or nanostructures (see, e.g., specification; page 4, lines 19-29) that covers first portions of the surface but leaves second portions exposed. The array causes the region to have a dynamically controllable hydrophobicity (e.g., page 5, lines 23-28; FIG. 3).

As further set forth in Claim 8, a chemically active substance (e.g., a pharmacological agent or drug; e.g., element 69; FIG. 3) is adhered to at least one of the exposed second portions of the stent surface. In order to control the release of the drug or agent into the body fluid, a control device (e.g., element 72, FIG. 6; element 82, FIG. 7) affixed to the tubular member

controls how body fluid penetrates the interstices of the array. To this end, an electrically conductive substrate (element 63; FIGs. 3, 5) is configured to be electrically isolated from the body fluid, and the control device applies a voltage between the array (and hence the fluid) and the substrate. Varying the voltage varies the penetration of the interstices of the array by the body fluid, thereby causing release of the agent or drug into the fluid.

As set forth in independent claim 18, an implantable stent (e.g., element 60; FIG. 5) comprises a tubular member including a conducting substrate (element 63; FIGs. 3, 5) and having an interior surface and an exterior surface, with a region of at least one of the surfaces being hydrophobic to a body fluid (e.g., layer 67; FIG. 3); the contact angle between a droplet of the body fluid (e.g., 40; FIG. 3) and the surface is greater than 90° (see, e.g., specification, page 7, lines 3-4). The hydrophobic surface region is provided with an array (e.g., element 62; FIGs. 3, 5) of pillar-like microstructures or nanostructures (see, e.g., specification; page 4, lines 19-29) that covers first portions of the surface. The array causes the region to have a dynamically controllable hydrophobicity (e.g., page 5, lines 23-28; FIG. 3) between a first state, in which the body fluid 40 is suspended over the top of the microstructures or nanostructures (e.g., fluid 40; FIG. 3), and a second state, in which the fluid penetrates the interstices of the microstructures or nanostructures (e.g., akin to fluid 10; FIG. 2). A medicinal substance (e.g., element 69; FIG. 3) is adhered to a second portion of the hydrophobic surface located in the interstices, and a control device (e.g., element 72, FIG. 6; element 82, FIG. 7) is affixed to the tubular member for applying voltage between the fluid and the substrate to vary the hydrophobicity, thereby releasing the medicinal substance into the body fluid when in the second state. The control device is actuatable from an *ex vivo* source (e.g., element 74, FIG. 6; element 84, FIG. 7).

VI. Grounds of Rejection To Be Reviewed

A. Whether claims 1-8, 12, 13, and 18-20 are obvious over **Bailey** in view of **Karwoski**, as applied by the Examiner.

B. Whether claims 1, 2, 5-7 and 9-11 are obvious over **Momma** in view of **Karwoski**, as applied by the Examiner.

C. Whether claims 1, 2, 5-7 and 15-17 are obvious over **Shastri** in view of **Karwoski**, as applied by the Examiner.

D. Whether claims 1 and 14 are obvious over **Oktay** in view of **Karwoski**, as applied by the Examiner.

E. Whether claim 21 is obvious in view of **Bailey** in view of **Karwoski** further in view of **Momma**, as applied by the Examiner.

VII. Argument

A. Although the Examiner has rejected claims 1-8, 12, 13, and 18-20 as being obvious over Bailey in view of Karwoski, he has (1) failed to demonstrate that patentably distinguishing features explicitly recited in these claims are taught or suggested by the combination of Bailey and Karwoski and (2) improperly combined the references.

CLAIMS 1-2 and 5-7

Claims 1-2 and 5-7 have been canceled by operation of the aforesaid amendment filed under 37 CFR § 41.33.

INDEPENDENT CLAIM 8

(1) **Patentable Features:** The implantable stent of independent claim 8 contains the following features that patentably distinguish over the proposed combination of Bailey and Karwoski:

- **Drug-Delivery Stent:** Bailey describes an implantable *in vivo* sensor. Karwoski describes an implantable vascular prosthesis having a non-thrombogenic fluorinated coating. Neither describes a drug-delivery stent. Neither describes a drug-delivery stent wherein the stent surface includes an array of microstructures or nanostructures and a drug or pharmacological agent is located in the interstices of the array. Neither describes applying voltage to the array to control the penetration of body fluid into the interstices of the array to cause the release of the drug or pharmacological agent into the body fluid.

- **Dynamic Control of Hydrophobicity:** Applicants' invention requires that an implantable drug delivery stent has a hydrophobic surface (claim 8, line 3) and that the surface hydrophobicity is ***dynamically controllable*** (claim 8, lines 6-7). For example, various embodiments of Applicants' invention include an array of microstructures or nanostructures (claim 8, lines 5-6) in a first portion of the surface and a control device affixed to the tubular member for varying the hydrophobicity (claim 8; lines 12-15).

Assuming, ***arguendo,*** that the proposed combination of the Bailey and Karwoski references is proper, the Examiner cites only page 10, lines 17-33 of Bailey for a purported teaching of the dynamic control of hydrophobicity. [Final Office Action, October 15, 2008, p. 4, lines 6-8; Office Action of November 19, 2009, page 3, lines 13-15] However, a careful reading of the cited section reveals nothing regarding hydrophobicity and, furthermore, nothing regarding its dynamic control. More specifically, with respect to Bailey, the Examiner states "Another stent [implantable sensor] is also disclosed that describes an array of microstructures or grooves and hydrophobicity can be controlled in a dynamic fashion, page 10, lines 17-33. The cellular response and its effect on the microstructure clearly effects hydrophobicity." However, this section of Bailey merely describes an endoluminal implant having a plurality of microgrooves on the luminal and/or abluminal surfaces thereof which facilitate improved endothelialization over a non-grooved implant. The Examiner's bald assertion that these grooves and/or the cellular response to them "clearly effects hydrophobicity" is pure speculation. Bailey does not describe a hydrophobic surface; nor is such a surface inherent in his device. Applicants have not waived their right to being provided, by the Examiner, with a basis in fact and/or technical reasoning to support his allegations of the inherency as required in M.P.E.P. § 2113. (See also, ***Ex parte Levy***, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). In the absence of such a basis, the rejection is improper.

In addition, even if a hydrophobic surface (i.e., as in the present claims) were inherently present in the proposed combination of Bailey and Karwoski, the Examiner

points to no section of the combination to support the notion that the grooves would be used to dynamically control such hydrophobicity as recited in the present claims. No such control is described. For this independent reason, the rejection would be improper.

- **Variable Penetration of Interstices:** Claim 8, lines 12-15, calls for a control device that varies the "penetration of the interstices of said array by said fluid, thereby causing release of said agent or drug into said fluid." This feature has not been adequately addressed by the Examiner in his rejection of claim 8. Instead, the Examiner merely offers an unsupported conclusion that Bailey's "fluid is ***capable of being suspended*** over the microstructures in a first state and ***then penetrates*** between the microstructures in a second state" (emphasis added). This functional statement is the very essence of Applicants' invention – the dynamic control of hydrophobicity in a microstructured drug delivery stent. But, the Examiner cites no section of the references, and provides no other evidence, to support such features. Instead, the Examiner is clearly and improperly simply using hindsight and Applicants' own teachings to find such features. Consequently, a ***prima facie*** case of obviousness has not been established.

(2) **Improper Combination:** The implantable stent of independent claim 8 recites:

> at least one of said surfaces [of a tubular member] being hydrophobic to a body fluid in that the contact angle between a droplet of said [body] fluid and said at least one surface is greater than 90°...(emphasis added)

The Examiner explicitly acknowledges that Bailey "does not explicitly state the surface has a contact angle greater than 90° when any drop of fluid contacts it." [Final Office Action of October 15, 2008, p. 4, lines 20-22; Office Action of November 19, 2009, p. 4, lines 5-6 (underlining added)]. In an attempt to overcome this deficiency of Bailey, the Examiner points to Karwoski's teaching "to coat the inner surfaces of prostheses with a coating that provides a hydrophobicity that a drop of body fluid will have a contact angle greater than 90° to give it a non-thrombogenic surface" and then asserts "It would have been obvious...to coat the inner

surface of the device [implantable sensor] of Bailey with the coating of Karwoski et al. to provide a hydrophobic surface...since...it reduces thrombogenicity." [Office Action of November 19, 2009, p. 4, lines 6-12 (underlining added)]

However, Karwoski teaches away from the proposed combination with Bailey. For example, Karwoski clearly teaches that "In general, the substrate [i.e., the surface of the prosthesis on which his hydrophobic coating is formed] should be composed of an ***organic*** material which can form carbon-carbon and carbon-fluorine covalent bonds" [col. 7, lines 37-39]. But, the Examiner admits that Bailey discloses devices made of ***metal*** [Bailey, pp. 6, 16; Final Office Action of October 15, 2008, p. 3, line 20; Office Action of November 19, 2009, p. 4, lines 5-6]. He cites no section of Bailey suggesting a device having an organic surface. Due to the chemical differences between the organic substrates of Karwoski's prostheses and the metal compositions of Bailey's device s, there is no reasonable expectation of success in modifying Bailey's inorganic metal device s to have the coatings that Karwoski teaches are usable on an organic substrate. That is, the Examiner has provided no evidence that the metal device s (substrates) of Bailey would form the "carbon-carbon and carbon-fluorine bonds" taught by Karwoski as desirable to attach his coatings to a surface. Therefore, it is respectfully submitted that it would not be obvious for one of ordinary skill in the art to apply the aforesaid teaching of Karwoski to the metal device s of Bailey.

DEPENDENT CLAIMS 3, 4, 12, 13

Dependent claims 3-4 and 12-13 are patentable at least by virtue of their dependence from independent claim 8 for the reasons set forth above and incorporated herein by reference.

INDEPENDENT CLAIM 18

(1) **Patentable Features:** The implantable stent of independent claim 18 contains the following features that patentably distinguish over the proposed combination of Bailey and Karwoski:

- **Drug-Delivery Stent:** Bailey describes an implantable *in vivo* sensor. Karwoski describes an implantable vascular prosthesis having a non-thrombogenic fluorinated

coating. Neither describes a drug-delivery stent. Neither describes a drug-delivery stent wherein the stent surface includes an array of microstructures or nanostructures and a drug or pharmacological agent is located in the interstices of the array. Neither describes applying voltage to the array to control the penetration of body fluid into the interstices of the array to cause the release of the drug or pharmacological agent into the body fluid.

- **Dynamic Control of Hydrophobicity:** Applicants' invention requires that an implantable drug delivery stent has a hydrophobic surface (claim 18, line 4) and that the surface hydrophobicity is ***dynamically controllable*** (claim 18, lines 7-8). For example, various embodiments of Applicants' invention include an array of microstructures or nanostructures (claim 18, lines 6-7) in a first portion of the surface and a control device affixed to the tubular member for varying the hydrophobicity (claim 18, lines 13-15).

  Assuming, ***arguendo***, that the proposed combination of the Bailey and Karwoski references is proper, the Examiner cites only page 10, lines 17-33 of Bailey for a purported teaching of the dynamic control of hydrophobicity. [Final Office Action, October 15, 2008, p. 4, lines 6-8; Office Action of November 19, 2009, page 3, lines 13-15] However, a careful reading of the cited section reveals nothing regarding hydrophobicity and, furthermore, nothing regarding its dynamic control. More specifically, with respect to Bailey, the Examiner states "Another stent [implantable sensor] is also disclosed that describes an array of microstructures or grooves and hydrophobicity can be controlled in a dynamic fashion, page 10, lines 17-33. The cellular response and its effect on the microstructure clearly effects hydrophobicity." However, this section of Bailey merely describes an endoluminal implant having a plurality of microgrooves on the luminal and/or abluminal surfaces thereof which facilitate improved endothelialization over a non-grooved implant. The Examiner's bald assertion that these grooves and/or the cellular response to them "clearly effects hydrophobicity" is pure speculation. Bailey does not describe a hydrophobic surface; nor is such a surface inherent in his device. Applicants have not waived their right to

being provided, by the Examiner, with a basis in fact and/or technical reasoning to support his allegations of the inherency as required in M.P.E.P. § 2113. (See also, ***Ex parte Levy***, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). In the absence of such a basis, the rejection is improper.

In addition, even if a hydrophobic surface (i.e., as in the present claims) were inherently present in the proposed combination of Bailey and Karwoski, the Examiner points to no section of the combination to support the notion that the grooves would be used to dynamically control such hydrophobicity as recited in the present claims. No such control is described. For this independent reason, the rejection would be improper.

- **Variable Penetration of Interstices:** Claim 18, lines 6-10 calls for two-state hydrophobicity – in a first state body fluid is suspended over the top of the microstructures or nanostructures, and in a second state body fluid penetrates the interstices of the microstructure or nanostructures. Furthermore, claim 18, lines 13-15 calls for a control device that "for applying a voltage between said fluid and said substrate to vary said hydrophobicity, thereby releasing said [medicinal] substance [from the interstices] into said body fluid when in said second state." These features have not been adequately addressed by the Examiner in his rejection of claim 18. Instead, the Examiner merely offers an unsupported conclusion that Bailey's "fluid is ***capable of being suspended*** over the microstructures in a first state and ***then penetrates*** between the microstructures in a second state" (emphasis added). This functional statement is the very essence of Applicants' invention – the dynamic control of hydrophobicity in a microstructured drug delivery stent. But, the Examiner cites no section of the references, and provides no other evidence, to support such features. Instead, the Examiner is clearly and improperly simply using hindsight and Applicants' own teachings to find such features. Consequently, a ***prima facie*** case of obviousness has not been established.

(2) **Improper Combination:** The implantable stent of independent claim 18, lines 4-5 recites:

> at least one of said surfaces [of a tubular member] being hydrophobic to a body fluid in that the contact angle between a droplet of said [body] fluid and said at least one surface is greater than 90°...(emphasis added)

The Examiner explicitly acknowledges that Bailey "does not explicitly state the surface has a contact angle greater than 90° when any drop of fluid contacts it." [Final Office Action of October 15, 2008, p. 4, lines 20-22; Office Action of November 19, 2009, p. 4, lines 5-6 (underlining added)]. In an attempt to overcome this deficiency of Bailey, the Examiner points to Karwoski's teaching "to coat the inner surfaces of prostheses with a coating that provides a hydrophobicity that a drop of body fluid will have a contact angle greater than 90° to give it a non-thrombogenic surface" and then asserts "It would have been obvious...to coat the inner surface of the device [implantable sensor] of Bailey with the coating of Karwoski et al. to provide a hydrophobic surface...since...it reduces thrombogenicity." [Office Action of November 19, 2009, p. 4, lines 6-12 (underlining added)]

However, Karwoski teaches away from the proposed combination with Bailey. For example, Karwoski clearly teaches that "In general, the substrate [i.e., the surface of the prosthesis on which his hydrophobic coating is formed] should be composed of an ***organic*** material which can form carbon-carbon and carbon-fluorine covalent bonds" [col. 7, lines 37-39]. But, the Examiner admits that Bailey discloses devices made of ***metal*** [Bailey, pp. 6, 16; Final Office Action of October 15, 2008, p. 3, line 20; Office Action of November 19, 2009, p. 4, lines 5-6]. He cites no section of Bailey suggesting a device having an organic surface. Due to the chemical differences between the organic substrates of Karwoski's prostheses and the metal compositions of Bailey's device s, there is no reasonable expectation of success in modifying Bailey's inorganic metal device s to have the coatings that Karwoski teaches are usable on an organic substrate. That is, the Examiner has provided no evidence that the metal devices (substrates) of Bailey would form the "carbon-carbon and carbon-fluorine bonds" taught by Karwoski as desirable to attach his coatings to a surface. Therefore, it is respectfully submitted that it would not be obvious for one of ordinary skill in the art to apply the aforesaid teaching of Karwoski to the metal devices of Bailey.

DEPENDENT CLAIM 19

Dependent claim 19 is patentable over Bailey and Karwoski, as applied by the Examiner, not only by virtue of its dependence from independent claim 18 for the reasons set forth above and incorporated herein by reference, but also because it contains additional patentably distinguishing features; to wit,

- **Electrically Isolated Zones:** Regarding dependent claim 19, the Examiner asserts that the feature that the exposed second surface includes "isolated zones" is an "arbitrary limitation and just like an elongate object, i.e. a stent has arbitrary ends, zones can be said to be present..." [Final Office Action, October 15, 2008, p. 4, line 13; Office Action of November 19, 2009, page 3, lines 19 ***et seq.***] Perhaps the Examiner's reference to the ends of an elongated object is a veiled attempt at an inherency argument; notwithstanding, he has conveniently ignored the fact that both of these claims require that actual zones of the microstructure be ***electrically isolated*** from one another ***and*** that separate zones of the microstructure carry separate doses of medicinal substances adhered thereto. Nothing in Bailey even remotely teaches or suggests this combination of features. In this regard, see also the following paragraph.
- **Tiled Hydrophobic Surface:** Claim 19 recites a stent design in which the array of nanostructures covers first portions of the stent surface, and second portions (e.g., the interstices of the array) remain exposed. This exposed portion is ***tiled*** in this embodiment of the invention; that is, divided into laterally separate, ***electrically isolated*** first and second zones, which have chemically active or medicinal substances adhered thereto. The control device actuates the release of the substances from selected zones. In applying Bailey to claim 19, the Examiner does not properly address the separate control of tiled, laterally separate, electrically isolated surface zones leading to the controlled release of substances from predetermined zones. Thus, a ***prima facie*** case of obviousness of claim 19 in view of Bailey and Karwoski has not been made out.

DEPENDENT CLAIM 20

Dependent claim 20 is patentable at least by virtue of its dependence from independent claim 18 and dependent claim 19 for the reasons set forth above and incorporated herein by reference.

B. Whether claims 1, 2, 5-7 and 9-11 are obvious over Momma in view of Karwoski, as applied by the Examiner.

CLAIMS 1, 2, 5-7 AND 9-11

Whether or not claims 1, 2, 5-7 and 9-11 are obvious over Momma in view of Karwoski, as applied by the Examiner, has been rendered moot by Applicants' amendment under 37 CFR § 41.33. More specifically, the aforesaid amendment canceled independent claim 1, as well as dependent claims 2 and 5-7, and rewrote dependent claim 8 in independent form to include all of the limitations of its base claim and all intervening dependent claims. Claim 8 was not rejected in view of the combination of Momma and Karwoski. Claims 9-11 depend from claim 8.

C. Whether claims 1, 2, 5-7 and 15-17 are obvious over Shastri in view of Karwoski, as applied by the Examiner.

CLAIMS 1, 2, 5-7 AND 15-17

Whether or not claims 1, 2, 5-7 and 15-17 are obvious over Shastri in view of Karwoski, as applied by the Examiner, has been rendered moot by Applicants' amendment under 37 CFR § 41.33. More specifically, the aforesaid amendment canceled independent claim 1, as well as dependent claims 2 and 5-7, and rewrote dependent claim 8 in independent form to include all of the limitations of its base claim and all intervening dependent claims. Claim 8 was not rejected in view of the combination of Shastri and Karwoski. Claims 15-17 depend from claim 8.

D. Whether claims 1 and 14 are obvious over Oktay in view of Karwoski, as applied by the Examiner.

CLAIMS 1 AND 14

Whether or not claims 1 and 14 are obvious over Oktay in view of Karwoski, as applied by the Examiner, has been rendered moot by Applicants' amendment under 37 CFR § 41.33. More specifically, the aforesaid amendment canceled independent claim 1 and rewrote dependent claim 8 in independent form to include all of the limitations of its base claim and all intervening dependent claims. Claim 8 was not rejected in view of the combination of Oktay and Karwoski. Claim 14 depends from claim 8.

E. Whether dependent claim 21 is obvious over Bailey in view of Karwoski and further in view of Momma, as applied by the Examiner.

DEPENDENT CLAIM 21

Claim 21 depends from dependent claim 19 which, in turn, depends from independent claim 18. Therefore, claim 21 is patentable at least by virtue of its dependence from claims 18 and 19 for the reasons set forth in Argument A, ***supra***, and incorporated herein by reference.

VIII. Claims Appendix

(a) Claims 3-4 and 8-21 remaining in the case and on appeal, assuming the amendment under 37 CFR § 41.37 is entered, are listed in Appendix VIII(a).

(b) Claims 1-21 remaining in the case and on appeal, assuming the amendment under 37 CFR § 41.37 is ***not*** entered, are listed in Appendix VIII(b).

IX. Evidence Appendix

No evidence appendix is attached.

X. Related Proceedings Appendix

No appendix of related proceedings is attached.

Respectfully,
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Att.

APPENDIX VIII(a)

Claims 3-4 and 8-21 Remaining on Appeal
Assuming Amendment under 37 CFR § 41.33 is Entered

3. The stent of claim 8, wherein said control device comprises an electronic device or an optical device.

4. The stent of claim 3, wherein said control device is remotely actuatable from an external source.

8. An implantable stent comprising:

a tubular member having an interior surface and an exterior surface,

at least one of said surfaces being hydrophobic to a body fluid in that the contact angle between a droplet of said fluid and said at least one surface is greater than 90°, and

a region of said at least one surface including an array of microstructures or nanostructures that covers first portions of said surface and leaves second portions exposed, said array causing said region to have a dynamically controllable hydrophobicity,

a chemically active substance adhered to at least one of said exposed second portions, said said substance comprising a pharmacological agent or a drug,

an electrically conductive substrate that is configured to be electrically isolated from body fluid in contact with said array of microstructures or nanostructures, and

a control device affixed to said tubular member for varying said hydrophobicity, wherein said control device is capable of applying a voltage between said array and said substrate to vary the penetration of the interstices of said array by said fluid, thereby causing release of said agent or drug into said fluid.

9. The stent of claim 8, wherein said array leaves second portions of said surface exposed, and further including

means for electrically isolating said array into laterally separate spatial zones,

at least two of said zones containing chemically active substances adhered to the exposed second portions thereof, and

wherein said control device is capable of causing the release of said substances of the separate zones at different times.

10. The stent of claim 9, wherein said substances are the same chemically active substances of the same or a different dose.

11. The stent of claim 9, wherein said substances are different chemically active substances.

12. The stent of claim 8, further including means for altering the shape of said stent *in vivo*.

13. The stent of claim 12, wherein said altering means is capable of changing the diameter of said tubular member.

14. The stent of claim 8, wherein said tubular member has an elongated slot that is coextensive with its length, thereby forming a pair of elongated edges that are movable relative to one another, and the stent further comprising a plurality of electrically controllable structures thereon, the structures capable of moving said edges and releasably latching said edges.

15. The stent of claim 8, wherein said tubular member comprises a semiconductor substrate and said array of microstructures or nanostructures is disposed on said substrate.

16. The stent of claim 15, wherein said tubular member further comprises a layer disposed on said substrate, said substrate and said layer having different thermal expansion coefficients.

17. The stent of claim 16, wherein said microstructures or nanostructures have at least one dimension that is in the range of 4 μm to 20 nm.

18. An implantable stent comprising

a tubular member including a conducting substrate, said member having an interior surface and an exterior surface,

at least one of said surfaces being hydrophobic to a body fluid in that the contact angle between a droplet of said fluid and said at least one surface is greater than 90°, and

a region of said at least one surface including an array of pillar-like microstructures or nanostructures that covers first portions of said surface, said array rendering the region to have a dynamically controllable hydrophobicity between a first state, in which said fluid is suspended over the top of said microstructures or nanostructures, and a second state, in which said fluid penetrates the interstices of said microstructures or nanostructures,

a medicinal substance adhered to an exposed second portion of said surface located in said interstices of said microstructures or nanostructures, and

a control device affixed to said tubular member for applying a voltage between said fluid and said substrate to vary said hydrophobicity, thereby releasing said substance into said body fluid when in said second state, said device being actuatable from an *ex vivo* source.

19. The stent of claim 18, wherein

said exposed second portion includes laterally separate first and second spatial zones electrically isolated from one another, each zone containing a medicinal substance adhered thereto, and

said control device is capable of causing the separate release of said substances from the first and second zones.

20. The stent of claim 19, wherein said substances adhered to said first and second zones are the same substance of the same or a different dose.

21. The stent of claim 19, wherein said substances adhered to said first and second zones are different substances.

APPENDIX VIII(b)

Claims 1-21 on Appeal
Assuming Amendment under 37 CFR § 41.33 is *not* Entered

1. An implantable stent comprising:

a tubular member having an interior surface and an exterior surface,

at least one of said surfaces being hydrophobic to a body fluid in that the contact angle between a droplet of said fluid and said at least one surface is greater than 90°, and

a region of said at least one surface including an array of microstructures or nanostructures that covers first portions of said surface, said array causing said region to have a dynamically controllable hydrophobicity.

2. The stent of claim 1, further including a control device affixed to said tubular member for varying said hydrophobicity.

3. The stent of claim 2, wherein said control device comprises an electronic device or an optical device.

4. The stent of claim 3, wherein said control device is remotely actuatable from an external source.

5. The stent of claim 1, wherein said array leaves second portions of said surface exposed, and further including a chemically active substance adhered to at least one of said exposed second portions.

6. The stent of claim 5, wherein said substance comprises a pharmacological agent or a drug.

7. The stent of claim 6, further including a control device affixed to said tubular member, said device being capable of releasing said agent or drug from said at least one second portion.

8. The stent of claim 7, further including

an electrically conductive substrate that is configured to be electrically isolated from body fluid in contact with said array of microstructures or nanostructures, and

wherein said control device is capable of applying a voltage between said array and said substrate to vary the penetration of the interstices of said array by said fluid, thereby causing release of said agent or drug into said fluid.

10. The stent of claim 1, wherein said array leaves second portions of said surface exposed, and further including

means for electrically isolating said array into laterally separate spatial zones,

at least two of said zones containing chemically active substances adhered to the exposed second portions thereof, and

wherein said control device is capable of causing the release of said substances of the separate zones at different times.

10. The stent of claim 9, wherein said substances are the same chemically active substances of the same or a different dose.

11. The stent of claim 9, wherein said substances are different chemically active substances.

12. The stent of claim 1, further including means for altering the shape of said stent *in vivo*.

13. The stent of claim 12, wherein said altering means is capable of changing the diameter of said tubular member.

14. The stent of claim 1, wherein said tubular member has an elongated slot that is coextensive with its length, thereby forming a pair of elongated edges that are movable relative to one another, and the stent further comprising a plurality of electrically controllable structures thereon, the structures capable of moving said edges and releasably latching said edges.

15. The stent of claim 1, wherein said tubular member comprises a semiconductor substrate and said array of microstructures or nanostructures is disposed on said substrate.

16. The stent of claim 15, wherein said tubular member further comprises a layer disposed on said substrate, said substrate and said layer having different thermal expansion coefficients.

17. The stent of claim 16, wherein said microstructures or nanostructures have at least one dimension that is in the range of 4 μm to 20 nm.

18. An implantable stent comprising

a tubular member including a conducting substrate, said member having an interior surface and an exterior surface,

at least one of said surfaces being hydrophobic to a body fluid in that the contact angle between a droplet of said fluid and said at least one surface is greater than 90°, and

a region of said at least one surface including an array of pillar-like microstructures or nanostructures that covers first portions of said surface, said array rendering the region to have a dynamically controllable hydrophobicity between a first state, in which said fluid is suspended over the top of said microstructures or nanostructures, and a second state, in which said fluid penetrates the interstices of said microstructures or nanostructures,

a medicinal substance adhered to an exposed second portion of said surface located in said interstices of said microstructures or nanostructures, and

a control device affixed to said tubular member for applying a voltage between said fluid and said substrate to vary said hydrophobicity, thereby releasing said substance into said body fluid when in said second state, said device being actuatable from an *ex vivo* source.

19. The stent of claim 18, wherein

said exposed second portion includes laterally separate first and second spatial zones electrically isolated from one another, each zone containing a medicinal substance adhered thereto, and

said control device is capable of causing the separate release of said substances from the first and second zones.

20. The stent of claim 19, wherein said substances adhered to said first and second zones are the same substance of the same or a different dose.

21. The stent of claim 19, wherein said substances adhered to said first and second zones are different substances.